



MARYLAND HEALTH CARE COMMISSION

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MEMORANDUM

TO: Commissioners

FROM: Eileen Fleck *E.F.*
Chief, Acute Care Policy and Planning

DATE: July 21, 2016

RE: Staff Recommendation for Proposed Permanent Regulations: State Health Plan for Facilities and Services: Organ Transplant Services (COMAR 10.24.15); Analysis of Comments Received

Maryland Health Care Commission (MHCC) staff is requesting that the Commission adopt as proposed permanent regulations a replacement COMAR 10.24.15: State Health Plan Chapter for Facilities and Services: Organ Transplant Services (“Chapter”). A draft Chapter was posted for informal public comment on May 5, 2016 and two organizations commented on this draft Chapter. A copy of the informal comments received is available on the MHCC web site.¹

**Analysis and Staff Recommendations Regarding
Informal Comments Received on the Draft Organ Transplant Services Chapter**

MHCC received informal public comments on a draft chapter of the State Health Plan for Facilities and Services: Organ Transplant Services, COMAR 10.24.15, from the Johns Hopkins Health System and from MedStar Health. A summary of the comments that were received is presented, followed by the MHCC staff’s analysis and recommendations.

.03 Issues and Policies

Quality of Care

MedStar Health commented that the draft Chapter’s discussion of the relationship between volume and outcomes for kidney transplants should state that the literature fully

¹http://mhcc.maryland.gov/mhcc/pages/hcfs/hcfs_shp/hcfs_shp.aspx

supports the relationship between higher volume centers and better outcomes. MedStar Health explained that its opinion was based on the two studies cited that support this conclusion. MedStar Health noted that one of the studies was published in a very high impact journal, the *American Journal of Transplantation*, and that the study concluded that there is a strong relationship between higher volumes and decreased mortality and morbidity for kidney transplants. MedStar Health also noted that study had not yet been contradicted.

Staff Analysis and Recommendation:

Staff recommends no changes in response to the comments from MedStar Health. Staff agrees with MedStar Health's conclusion that there is a relationship between higher volume centers and better outcomes for kidney transplant recipients based on the literature cited. However, Staff concludes that the emphasis on the studies' inability to identify a clear minimum threshold standard is appropriate, given the limited number of studies examining the relationship between volume and outcomes for kidney transplants. This approach is also consistent with the decision to maintain the current minimum and threshold volume standards for adult kidney transplants.

Access to Care

The Johns Hopkins Health System (JHHS) recommended that two additional studies be cited in the discussion of the relationship between competition among organ transplant programs and patient outcomes. JHHS also requested clarification of the conclusions of one study, "Temporal Analysis of Market Competition and Density in Renal Transplantation Volume and Outcome," published in 2016. JHHS noted that the statement in the policy discussion (page 18) that "[m]arket competition was not associated with a higher number of transplants" contradicts another statement in the study cited. JHHS explained that the authors concluded that more transplant centers were associated with a greater number of kidney transplants without compromising the success of the procedure. JHHS recommended that the study "Market Competition and Density in Liver Transplantation: Relationship to Volume and Outcomes" published in the *Journal of the American College of Surgery* (2015) also be cited and quoted text from the conclusions section of this article.

JHHS also suggested that an additional study, "Following the Organ Supply: Assessing the Benefit of Inter-DSA Travel in Liver Transplantation" published in *Transplantation* in 2013, be referenced in the discussion of barriers to access. JHHS stated its belief that this study shows that the presence or absence of a high performing center in a given geographic area has a disparate impact on mortality, based on socioeconomic status and ability to travel for care.

Staff Analysis and Recommendations:

Staff agrees that the discussion of the literature cited required clarification and a correction. Staff made changes to address the concern raised regarding the study, "Temporal Analysis of Market Competition and Density in Renal Transplantation Volume and Outcome." However, the specific sentence quoted by JHHS was not included because Staff concludes that it

is inconsistent with other statements made by the authors that are supported by the data presented.

Staff has made changes to the draft Chapter to include discussion of one of the two studies recommended by JHHS -- the study "Market Competition and Density in Liver Transplantation: Relationship to Volume and Outcomes." Staff chose not to include the other study, "Following the Organ Supply: Assessing the Benefit of Inter-DSA Travel in Liver Transplantation" because of the small percentage of patients who receive liver transplants by traveling to another DSA. Staff notes that the study's authors stated that patients who choose to travel to another DSA after initial listing (the cohort studied) comprise between two and three percent of all patients listed for a liver transplant. Although Staff agrees that the study provides insight into the sources of disparities for liver transplant patients, Staff disagrees that the conclusions of the study should be used generally as a basis for drawing conclusions about the role of competition among liver transplant programs.

.04 Docketing Rules

JHHS recommended eliminating Part A of the Docketing Rules, stating that potentially a new program would be precluded from submitting an application even though access to transplant services is inadequate. JHHS explained its view that that failure of an existing organ transplant program to exceed the threshold volume for the draft Chapter's required most recent three years may be an indicator of a program's inadequate performance rather than an indicator of a lack of need in the region or of access barriers. JHHS specifically expressed concern about a program that performs greater than the minimum number of cases, but less than the threshold standard. JHHS proposed that the Commission should be responsible for evaluating the evidence to determine if a new program is warranted.

Staff Analysis and Recommendations:

Staff disagrees that the docketing rule regarding the use of threshold volume standards for many types of organ transplant programs should be deleted. However, Staff modified the language to refer to meeting the threshold volume standard on average over the three most recent years. This change reduces the probability that a fluctuation in a single year eliminates the opportunity for an application to be docketed. It also reduces the probability that a recently approved program that requires time to ramp up in volume will delay the opportunity for an application to be docketed as a result of low volume in the first year, despite a strong performance in the two subsequent years. Staff also added language stating that the case volume for an organ transplant service located outside of Maryland that fails to meet and maintain minimum volume requirements may be disregarded, if a similarly situated organ transplant service in Maryland for the same type of organ would be considered for closure by the Commission if it were located in Maryland.

Informal public comments submitted to MHCC did not address the potential for a negative impact on Maryland hospitals as a result of timing issues with the CON processes in

Virginia and the District of Columbia. However, Staff recommends the addition of language to the docketing rules to provide that the Commission may institute or continue a CON review to establish an organ transplant service in Maryland if a letter of intent to establish a transplant service is submitted prior to the completion of a CON process to establish the same type of organ transplant service outside of Maryland but within the health planning region.

.05 Standards

JHHS requested clarification regarding the requirement for hematopoietic stem cell bone marrow transplant programs to obtain accreditation by the Foundation for the Accreditation of Cellular Therapy (FACT). JHHS noted inconsistent standards in the draft Chapter. Specifically, Paragraph .05A(2)(b) requires accreditation within the first two years of operation, whereas Paragraph .05B(6)(b) provides that a program must meet accreditation requirements within the first three years of operation.

JHHS also requested that the MHCC staff reinstate language from the previous Organ Transplant Services Chapter that requires an organ transplant program to be located in, or closely affiliated with a teaching hospital. JHHS did not further explain the basis for this recommendation.

Staff Analysis and Recommendations:

Staff agrees that the language regarding the requirement to obtain accreditation by FACT should be consistent in the Chapter and revised the language to consistently state that accreditation is required within the first two years of operation.

As for the second comment made by JHHS, Staff continues to believe that the existing Organ Transplant Chapter's requirement that an organ transplant program be located in or closely affiliated with a teaching hospital should not be continued. The work group composed of representatives from the Centers for Medicare & Medicaid Services, the United Network for Organ Sharing, Organ Procurement Organizations, and hospitals with organ transplant programs specifically discussed whether to maintain this requirement and recommended deleting it.

.06 Definitions

JHHS requested that a definition for "adult" be included. JHHS noted that Tables 2 and 3 on pages 20 and 22 list separate threshold and minimum volumes for adult and pediatric kidney transplant programs, and that the terms "Pediatric" and "pediatric program" are already included in the definitions section. The Johns Hopkins Health System stated that the addition of this definition will help clarify the application of volume requirements for programs performing both adult and pediatric transplants. JHHS specifically proposed the following definition:

Adult refers to patients age 18 or older. An adult program is one that serves a majority of patients over age 18.

Staff Analysis and Recommendation:

Staff agrees with JHHS's recommendation to include a definition for adult and included the proposed definition. In addition, Staff revised the definitions for "organ transplant" "transplant." and deleted the definitions for "organ" and "transplantation."